

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
	Telephone Interview .....	37	1	1

Dated: April 6, 2010.

**Maryam I. Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Advisory Committee on Immunization Practices: Notice of Charter Renewal**

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through April 1, 2012.

For information, contact Larry Pickering, M.D., Executive Secretary, Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention, Department of Health and Human Services, 1600 Clifton Road, NE., Mailstop E05, Atlanta, Georgia 30333, telephone 404/639-8767 or fax 404/639-8626.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 6, 2010.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-D-0166]

**International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Draft Guidance for Industry on Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Marker Residue Depletion Studies to Establish Product Withdrawal Periods (VICH GL48); Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#207) entitled “Draft Guidance for Industry on Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Marker Residue Depletion Studies to Establish Product Withdrawal Periods,” (VICH GL48). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance document is intended to provide study design recommendations which will facilitate the universal acceptance of the generated residue depletion data to fulfill this recommendation.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by May 12, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Julia Oriani, Center for Veterinary Medicine (HFV-151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8204, e-mail: [julia.oriani@fda.hhs.gov](mailto:julia.oriani@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry (#207) entitled “Draft Guidance for Industry on Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Marker Residue Depletion Studies to Establish Product Withdrawal Periods,” (VICH GL48). In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union (EU), Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal